

**Department of Health and Human Services  
National Institutes of Health/NIAID  
Bethesda, MD**

**Development of a Clinical Trial Plan for Pandemic Influenza Vaccines**

**Monday, September 22**

8:30 a.m. - 8:45 a.m.                      **WELCOME/INTRODUCTION**  
Linda Lambert

**Morning Session**

Moderator:                                  Arnold Monto

8:45 a.m. - 9:15 a.m.                      **VACCINE EXPERIENCES/LESSONS FROM THE PAST**  
Robert Couch

9:15 a.m. - 9:45 a.m.                      **RECENT VACCINE EXPERIENCE WITH NOVEL ANTIGENS**  
Karl Nicholson

9:45 a.m. - 10:15 a.m.                      **POTENTIAL PANDEMIC VIRUSES: PRIORITY FOR VACCINE  
EVALUATIONS**  
Robert Webster  
Introductory remarks by Klaus Stöhr

10:15 a.m. - 10:45 a.m.                      **BREAK**

10:45 a.m. - 11:15 a.m.                      **MANUFACTURING RISK ASSESSMENT UPDATE and EUROPEAN  
REGULATORY UPDATE**  
John Wood  
Introductory remarks by Klaus Stöhr

11:15 a.m. – 11:45 a.m.                      **REGULATORY ISSUES**  
Karen Midthun

NOON – 1:00 p.m.                              **LUNCH**

# **Development of a Clinical Trial Plan for Pandemic Influenza Vaccines**

## **Workshop Agenda**

### **Monday, September 22**

#### **Afternoon Session**

#### **WORKSHOP DISCUSSIONS: Establishing Needs and Variables for Clinical Evaluation**

#### **I. PRECLINICAL TOOLS AND ISSUES**

1:00 p.m.

**OVERVIEW OF THE ISSUES AND OPTIONS FOR DISCUSSION**  
Nancy Cox

**Moderators:**

Roland Levandowski  
Linda Lambert

#### **POINTS FOR DISCUSSION**

AVAILABILITY OF PANDEMIC REFERENCE STRAINS  
SUBSTRATES FOR PRODUCTION  
AVAILABILITY OF REAGENTS  
SAFETY CONSIDERATIONS  
OTHER REGULATORY ISSUES

#### **BREAK**

#### **II. CLINICAL TRIALS: Interpandemic and Pandemic**

**OVERVIEW OF THE ISSUES AND OPTIONS FOR DISCUSSION**  
John Treanor

**Moderators:**

Karl Nicholson  
John Treanor

#### **POINTS FOR DISCUSSION**

VIRUSES/VACCINES TO BE EVALUATED  
VACCINE PREPARATIONS TO BE EVALUATED  
DOSE RANGE AND SCHEDULE  
AGES FOR EVALUATION  
IMMUNOLOGICAL ASSESSMENTS  
ADJUVANTS

# **Development of a Clinical Trial Plan for Pandemic Influenza Vaccines**

## **Workshop Agenda**

### **Tuesday, September 23**

8:30 a.m. – Noon

#### **DRAFT PLAN FOR CLINICAL TRIALS**

**Presentation and discussions of key points raised from Monday**

Linda Lambert

Robert Couch